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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 17 1997

WARNING LETTER

Ref:OC:I1-1762

via Federal Express

Mr. Dave Leavenworth
Entertainment Technical Productions
Knott's Berry Farm
8039 Beach Blvd.
Buena Park, California 90620

Dear Mr. Leavenworth:

Thank you and your staff for the courtesy and cooperation extended to the FDA representatives during an inspection of the laser light show installations at Knott's Berry Farm on August 25, 1997.

This letter also confirms items of noncompliance with the Federal performance standard for laser products and your variances for production of laser light shows at Knott's Berry Farm. The noncompliances were encountered during an evaluation of the equipment and performances of the laser light shows at the Good Time Theater and the Reflection Lake locations. The evaluation was conducted by Frank W. Mackison, Consumer Safety Officer, Office of Compliance, and Ms. Serrah Namini, Electro-Optics Specialist, FDA Los Angeles District Office. Ms. Susan Jensen and Ms. Cynthia Faville of this office also participated in the inspection.

The following items of noncompliance were noted during the inspection:

1. 21 CFR 1040.10(f)(1): Protective housing. The protective housing at the left end of the laser projector at the Good Time Theater contained gaps in the corner seam and in the space between the laser output aperture and the projector housing that could permit human access to laser radiation.

2. Variance (No. 95V-0251) Paragraph H, Certification label. The show for the Good Time Theater lacked a certification label as required by this paragraph of the variance.

3. Variance (No. 79V-0257) Attachment A, Paragraphs 4 and 9. Observation of the performance of the water fountain and laser show at the Reflection Lake location revealed

that laser beams were being terminated in an area accessible to park patrons. This permitted possible exposure of patrons to laser radiation in excess of Class I as the beams scanned across part of the routes traversed by the log ride and the stagecoach ride.

4. Variance (No. 79V-0257) Attachment A, Paragraph 11. Quality control procedures. There was failure to adequately implement written quality control procedures, the "Laser Display System Quality Control Checklist" for the Reflection Lake Liquid Laser Show on the night of August 25. This failure contributed to the occurrence of the noncompliance noted in item 3.

5. It was noted at the time of this inspection that the variance No. 95V-0251 for the Good Time Theater expired on August 21. We have, however, now received your request for renewal of that variance and your request is under consideration. It is further noted that the laser production for the Nu Wave Theater was to cease operation on Labor Day, September 1, and would not be produced after that date.

The following observation and recommendation relate to your record keeping procedures.

Although problems encountered in daily operation of the shows are recorded in a log book maintained at each show, there was no convenient way to determine what actions, if any, were taken to correct problems. Problems that occur should be cross referenced to the actions taken to correct them.

At the conclusion of the inspection, the above items were discussed with you. You stated that all items would be corrected.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. The production or performing of a laser light show is an act of manufacturing. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to response to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violation of the Act are subject to civil penalties of up to $1,000 per violation and up to a maximum penalty of $300,000 without further notification by the FDA. You are not being requested to submit a formal corrective action plan at this time, however, all of your equipment and future performances must comply with the Federal performance standard and variance. Person failing to correct violations may be subject to regulatory action. If you feel that the alleged failures to comply do not exist, you may present your views and evidence within 15 days of the date of this letter . You must response to each of the items listed above stating what action you have taken or will take and what changes you have or will make to your equipment and shows to achieve full compliance. Your response should be submitted

within 15 days of the date of receipt of this letter, clearly referencing the appropriate variance number for each show.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a copy of your response to: Director, Compliance Branch, Los Angeles District Office, Food and Drug Administration, 19900 Mac Arthur Boulevard, Suite 300, Irvine, California 92612-2445. If you have any questions regarding the above cited items performance requirements, please contact Frank W. Mackison at (301) 594-4654.

Sincerely yours,

Larry D. Spears for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health